

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2001 list were published in the Federal Register in August 2001.

New Approvals

NADA Number: 141-188

Trade Name: Marquis™
Ingredients: Ponazuril
Sponsor: Bayer Animal Health
Approval Date: July 19, 2001
Status: Prescription only
Route: Oral
Species: Equine
Drug Form: Paste
Concentration: 15% w/w ponazuril
Indications: For the treatment of Equine Protozoal Myeloencephalitis (EPM) caused by *Sarcocystis neurona*.
Patent No.: 5,833,095 Expiration date: August 7, 2017
Exclusivity: 5 years

21CFR 520.1855

Change of Sponsor Name and Address

From: Orion Corp. ORION-FARMOS
P.O. Box 425
SF-20101 Turku, Finland
Drug labeler code: 052483

To: Orion Corp.
Orionintie 1
02200 Espoo, Finland
Drug labeler code: 052483

Withdrawals

NADA Number: 111-637

Trade Name: Tylosin Type A Medicated Article
Sponsor: Alpharma, Inc.
Date: August 13, 2001

NADA Number: 032-984

Trade Name: Cerumite
Sponsor: Evsco Pharmaceuticals, An Affiliate of IGI, Inc.
Date: August 27, 2001

NADA Number: 055-005

Trade Name: Liquichlor with Cerumene
Sponsor: Evsco Pharmaceuticals, An Affiliate of IGI, Inc.
Date: August 27, 2001

Actions Taken by FDA Center for Veterinary Medicine

Suitability Petition Action

Number:	01P-0349/CP1
Sponsor:	Smart Drug Systems, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Ivomec [®] , Merial Ltd., NADA 128-409 by the following characteristics: The generic product will consist of a different dosage form (compressed rod) and strength (35-60%) from the pioneer.
Action:	Filed August 10, 2001.
Petition:	00P-1486/PRC1
Sponsor:	Equi Aid Products, Inc.
Reason:	Request permission for reconsideration to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, ivermectin (Eqvalan [®]), Merial Ltd., NADA 134-314 by the following characteristics: the generic product will consist of a different dosage form ('chewable') and strength (22.7 milligrams per 'chewable') from the pioneer.
Action:	Filed August 16, 2001.